Maryland
DEPARTMENT OF HEALTH

Ocrevus (Ocrelizumab)

Ocrevus will be considered for coverage for the treatment of primary progressive multiple sclerosis (PPMS) and relapsing forms of multiple sclerosis in adults when all of the criteria below are met, confirmed with supporting medical documentation.

I. Criteria for Initial Approval

PPMS – Primary Progressive Multiple Sclerosis

Ocrevus is FDA approved for the treatment of primary progressive multiple sclerosis (PPMS) when **ALL** of the following criteria are met:

- Diagnosis of primary progressive multiple sclerosis (PPMS).
- Patient is an adult greater than or equal to 18 years old.
- Prescribed by, or in consultation with a neurologist.
- Does not have active Hepatitis B infection (screened prior to initiating treatment negative HBsAg and anti- HBV testing)
- Provider agrees to monitor for evidence of infections.
- Provider agrees to monitor for evidence of malignancies.
- Females of reproductive potential will have a documented negative pregnancy test prior to initiation of therapy and be advised to use effective contraception during treatment with Ocrevus and for 6 months after the last dose.
- Inform patients that currently no data on the presence of ocrelizumab in human milk, the effects on the breastfed infant, or the effects of the drug on milk production.
- Patient is not receiving Ocrevus in combination with any of the following:
    - Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide)
    - B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab)
    - Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone);

Relapsing forms of MS: Relapsing-Remitting Multiple Sclerosis (RRMS), Secondary Progressive with relapses (SPMS), and clinically isolated syndrome (CIS).

Ocrevus is FDA approved for the treatment of Relapsing forms of MS: Relapsing-Remitting Multiple Sclerosis (RRMS), Secondary – Progressive with relapses (SPMS) and clinically isolated syndrome (CIS) when ALL of the following criteria are met:

- Diagnosis of a form of relapsing multiple sclerosis.
- Patient is an adult greater than or equal to 18 years old.
- .Prescribed by, or in consultation with a neurologist.
- Does not have active Hepatitis B infection (Screened prior to initiating treatment negative HBsAg and anti- HBV testing).
- Provider agrees to monitor for infections.
- Provider agrees to monitor for malignancies.
- Females of reproductive potential will have a documented negative pregnancy test prior to initiation of therapy and be advised to use effective contraception during treatment with Ocrevus and for 6 months after the last dose.
- Inform patients that currently no data on the presence of ocrelizumab in human milk, the effects on the breastfed infant, or the effects of the drug on milk production.
- Patient is not receiving ocrelizumab in combination with any of the following:
    - Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide).
    - B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab).
    - Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone).

II. Criteria for Continuation of Therapy

All of the criteria for initial therapy (in Section I.) must be met; **AND**

- Documentation of positive clinical response to ocrelizumab therapy.

III. Dosing/Administration

Ocrevus must be administered according to the current FDA labeling guidelines for dosage and timing. The recommended dosing is as follows:

- Initial dosing: One time 300 mg IV on days 1 and 15 of initial therapy.
- Continued dosing: One 600 mg IV dose every 6 months.

IV. Length of Authorization For initial therapy

Ocrevus will be authorized for 6 months when criteria are met. Continuing therapy with Ocrevus will be authorized for 12 months.

V. Billing Code/Information

HCPCS Code: J2350 - Injection, ocrelizumab, 1 mg; 1 mg = 1 billable unit

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 7/28/2020
Last Reviewed Date: